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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS SCHULTZ,
BRADLEY A. CLARK, and ANGELA FALZONE

Appeal 2009-014705
Application 10/022,138
Technology Center 1600

Decided: April 29, 2010

Before ERIC GRIMES, DONALD E. ADAMS, and LORA M. GREEN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an oral steroid hormone product. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 1, 6 and 7 are on appeal. Claim 1 is representative and reads as follows:

1. An oral steroid hormone product having improved dissolution and release rate properties, said product comprising norgestimate in admixture with lactose, wherein substantially all of said norgestimate is in non-crystalline form and wherein said lactose stabilizes said norgestimate in its non-crystalline form.

I.

Issue

The Examiner has rejected claims 1, 6 and 7 under 35 U.S.C. § 103(a) as being obvious in view of Gast,[1] Morita,[2] Merck,[3] Jain,[4] Sebhatu,[5] and Buckton[6] (Ans. 4[7]). The Examiner has also rejected claims 1, 6, and 7 under 35 U.S.C. § 103(a) as being obvious in view of de Haan[8] and Merck

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[1] Gast et al., US 5,858,405, Jan. 12, 1999
[2] Masami Morita et al., *Physicochemical Properties of Crystalline Lactose. II. Effect of Crystallinity on Mechanical and Structural Properties,* 32 CHEM. PHARM. BULL. 4076-4083 (1984)
[3] S. Budavari (Editor) The Merck Index, 12th ed., p. 632 (1996)
[4] R. Jain et al., *Stability of a Hydrophobic drug in presence of hydrous and anhydrous lactose,* 46 EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS 177-182 (1998)
[5] Tesfai Sebhatu et al., *Assessment of the degree of disorder in crystalline solids by isothermal microcalorimetry,* 104 INTERNATIONAL JOURNAL OF PHARMACEUTICS 135-144 (1994)
[6] Graham Buckton et al., *The influence of additives on the recrystallisation of amorphous spray dried lactose,* 121 INTERNATIONAL JOURNAL OF PHARMACEUTICS 81-87 (1995)
[7] The Examiner also cited a reference by "Rialker et al." as part of the basis of the rejection (Ans. 4) but did not list a reference by Rialker et al. as part of the "Evidence Relied Upon" (Ans. 3) or otherwise identify the reference

(Ans. 5). Because the same issue is dispositive with respect to both rejections, we will consider them together.

The Examiner finds that Morita, Jain, Sebhatu, and Buckton teach the use of lactose in pharmaceutical preparations (Ans. 3). The Examiner finds that Gast discloses "a hormonal product with an excipient in crystalline and non-crystalline form" (Ans. 4) but does not teach a "non-crystalline steroid hormone" (*id.*). The Examiner finds that Merck discloses "that estrone *can be* crystallized which means that it was *not* crystalline before" (*id.* at 5). The Examiner concludes that the claimed composition would have been obvious because Merck "show[s] that estrone exists in both non-crystalline and crystalline forms" (*id.* at 5).

With regard to the second ground of rejection, the Examiner finds that de Haan discloses pharmaceutical preparations containing steroidal agents in combination with an excipient that can be lactose (Ans. 6). The Examiner also finds that de Haan discloses a tablet containing progesterone, and finds that "[n]orgestimate is progesterone" (*id.*). As before, the Examiner finds that Merck discloses "that estrone *can be* crystallized" (*id.*), and concludes that this teaching would have made obvious the claimed composition.

Appellants contend that none of the cited references disclose or suggest a product comprising norgestimate such that substantially all of the norgestimate is in non-crystalline form (Appeal Br. 9-11).

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being cited. Since the Examiner has not provided Appellants or us with adequate notice of the source of the evidence allegedly provided by Rialker et al., we have not considered it.

[8] De Haan, EP 0503521 A1, Sept. 16, 1992

The issue with respect to each of the rejections is: Does the evidence of record support the Examiner's conclusion that the cited references suggest a product comprising norgestimate such that substantially all of the norgestimate is in non-crystalline form?

Findings of Fact

1. Gast discloses a "combination progestin/estrogen oral contraceptive.... Particularly preferred progestins of this invention are trimegestone, dienogest, and drospirenone. (Gast, abstract).

2. Gast discloses, in the background prior art, that norgestimate is a known component of contraceptives (*id.* at col. 2, l. 48; col. 3, ll. 14 and 25).

3. Gast discloses that "[p]referred estrogens include ... estrone or a salt thereof" (*id.* at col. 7, ll. 10-12).

4. Merck discloses that estrone exists in three crystal phases (Merck 632).

5. De Haan discloses "dry pharmaceutical preparations containing ultra-low doses of one or more micronized steroidal medicinal agents in combination with a primary excipient" (de Haan, 3: 21-23).

6. De Haan discloses that "[s]teroids used in the compositions and processes of the invention are preferably estrogens, progestogens, or both" (*id.* at 4: 32-33).

7. De Haan discloses that "[p]referred progestogens for use with the invention include 3-ketodesogestrel ('etonogestrel'), desogestrel, levo-norgestrel, norgestrel, gestodene, and other compounds with similar progestogenic activity" (*id.* at 4: 34-35).

Principles of Law

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993).

Analysis

Claim 1 is directed to an oral steroid hormone product comprising norgestimate, where substantially all of the norgestimate is in non-crystalline form. Appellants contend that the cited references do not disclose or suggest this limitation (Appeal Br. 9-11).

The Examiner responds that Gast discloses norgestimate as a progestin, and progestins in combination with estrogen, and that Merck discloses that estrone, an estrogen, exists in both non-crystalline and crystalline forms (Ans. 7-8).

Appellants' arguments are persuasive that the Examiner has not adequately explained how the cited references suggest the claimed non-crystalline norgestimate. While Gast discloses that norgestimate has been used in contraceptive products before, it does not disclose whether the norgestimate was in crystalline or non-crystalline form. The Examiner has not pointed to any disclosure of norgestimate in de Haan. Thus, none of the cited references disclose non-crystalline norgestimate.

The Examiner's reasoning, as we understand it, is that Merck's disclosure of estrone as having a crystalline form suggests that it also has a non-crystalline form, and therefore so does the different steroid hormone norgestimate. This reasoning is not persuasive. The Examiner has not

adequately explained why the existence of a non-crystalline form of a certain compound would have made obvious the use of a non-crystalline form of a different compound in the composition disclosed by Gast or de Haan.

Thus, we are compelled to reverse the rejection of claim 1 as being obvious in view of Gast, Morita, Merck, Jain, Sebhatu, and Buckton, as well as the rejection of claim 1 as being obvious in view of de Haan and Merck. The rejections of claims 6 and 7, which depend from claim 1, are also reversed for the same reason.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that the cited references suggest a product comprising norgestimate such that substantially all of the norgestimate is in non-crystalline form.

SUMMARY

We reverse both rejections of claim 1, 6 and 7 under 35 U.S.C. § 103(a).

REVERSED

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